DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 22, 2014

Evergreen Orthopedic Research Lab *dba* Operative
Mr. Jeff Stepanian
Chief Operating Officer
11321 Northeast 120th Street
Kirkland, Washington 98034

Re: K140689
Trade/Device Name: iKnee Distal Femoral Cutting Guide
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 10, 2014
Received: August 13, 2014

Dear Mr. Stepanian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140689

Device Name
iKnee Distal Femoral Cutting Guide

Indications for Use *(Describe)*
The iKnee Distal Femoral Cutting Guide is indicated for use as a stereotaxic accessory instrument that acts as a cutting guide for the distal femur during a total knee arthroplasty using computer navigation. The iKnee Distal Femoral Cutting Guide requires the use of a Stryker Smart Instrument navigation tracker in conjunction with a compatible Stryker navigation system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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5. 510(k) SUMMARY:

NAME OF FIRM:	Evergreen Orthopedics Research Lab d/b/a Operativ 11321 NE 120th St. Kirkland, WA 98034
510(k) CONTACT:	Jeff Stepanian, COO Jeff.stepanian@opertiv.com (425) 284-7262
DATE PREPARED:	August 22th, 2014
TRADE NAME:	iKnee Distal Femoral Cutting Guide
COMMON NAME:	Distal Femoral Cutting Guide
DEVICE CLASSIFICATION NAME:	Stereotaxic Instrument 21 CFR 882.4560
DEVICE PRODUCT CODE:	OLO
PRODUCT CLASS:	II
SUBSTANTIALLY EQUIVALENT DEVICES:	Zimmer (K052425) (CAS EM Distal Cut Guide Assembly) (Item Number 20-5970-001-00) Stryker Navigation System – Knee Module (K010204) Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090) (K010204)

DEVICE DESCRIPTION:

The Operativ iKnee Distal Femoral Cutting Guide is a device used to cut the distal femur during a computer navigated total knee arthroplasty. The iKnee Distal Femoral Cutting Guide can control all three plains (varus/valgus, flexion/extension and depth) independently to allow for easy adjustments to ensure accuracy and ease of use. The iKnee Distal Femoral Cutting

Guide is used with the Stryker Navigation Unit and associated stereotaxic Smart Instruments (K010204) to cut the distal femur during a total knee arthroplasty.

INTENDED USE:

The iKnee Distal Femoral Cutting Guide is indicated for use as a stereotaxic accessory instrument that acts as a cutting guide for the distal femur during a total knee arthroplasty using computer navigation. The iKnee Distal Femoral Cutting Guide requires the use of a Stryker Smart Instrument navigation tracker in conjunction with a compatible Stryker navigation system.

TECHNOLOGICAL COMPARISON to the PREDICATE DEVICE:

The iKnee Distal Femoral Cutting Guide like its predicate device Zimmer CAS EM Distal Cut Guide Assembly (K052425) (Item Number 20-5970-001-00) both cut the distal femur during a navigated total knee arthroplasty. The subject device works with the Stryker Navigation unit (K010204) whereas the predicate device works with its proprietary navigation unit. Both the subject device and the predicate device reference the same initiating point on the distal femur (approximate exit point of the mechanical axis). The subject device uses a 3.2mm partially threaded pin to enter that point and hold the cutting device in place while adjustments are made. The predicate device uses a 8mm NavPositioner Ball Screw (K052425) (item number 20-5970-000-00) or CAS Spike Adapter (K052425) (item number 20-5970-050-11) that serves the same function as the subject device 3.2mm partially threaded pin.

The subject device is made up of two pieces, a cutting block and cutting jig that are assembled before the surgery to make one complete piece. The predicate device is modular and has multiple pieces that lock together during the surgery to make-up the completed cutting guide. This difference does not impact patient safety.

Once the subject device and predicate device are in place the varus/valgus and flexion/extension alignments are navigated to the surgeons' desired angles. This is the same for both devices. Once those angles are locked in place (thumb screw for predicate device and 3.2mm pin for subject device) the depth of cut is then set by thumb adjustment to desired depth. This is the same for both the subject and predicate devices. The distal femoral cutting block is then locked in place with two 3.2mm pins. This is the same for both the subject and predicate devices. The varus/valgus, flexion/extension and depth of cut are then depicted on the computer screen. Both the subject device and the predicate device are then dismantled leaving the cutting block in place with the two 3.2mm pins holding the cutting block.

The subject device has additional features the predicate device does not have 1) the cutting block and jig can be left in place together if desired by the surgeon. This provides a ridged system for the cutting guide 2) the cutting block has a slotted or non-slotted option so the surgeon can choose which option they desire 3) the cutting block has adjustable pin holes that allow for further correction of depth +2/-2mm if needed. The predicate device does not have

those features. The distal femoral bone cut for the subject device and the predicate device are then completed in the same fashion.

CONCLUSION:

The subject device and the predicate device both cut the distal end of the femur during a computer navigated total knee arthroplasty. The subject device and the predicate device are extremely similar in how the device is utilized during a computer navigated total knee arthroplasty. The subject device and the predicate device have the same initial insertion site; varus/valgus is adjusted in a similar fashion as is the flexion/extension and depth of cut. The function/intended use (cutting block for distal femur during navigated total knee replacement) is the same for both the subject device and the predicate device. Both devices are made of stainless steel. Based on to the material of the devices and the technological characteristics there is sufficient information to support a determination of substantial equivalence. The subject device does have additional features that the predicate device does not have such as 1) the cutting block and jig can be left in place together if desired by the surgeon. This provides a ridged system for the cutting guide 2) the cutting block has a slotted or non-slotted option so the surgeon can choose which option they desire 3) the cutting block has adjustable pin holes that allow for further correction of depth +2/-2mm if needed.

NON-CLINICAL PERFORMANCE TESTING

Bench testing was performed to evaluate 1) a functional toggle check between the subject device and the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401) compared to the Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090). This test was performed to show that the iKnee Distal Femoral Cutting Guide along with the Stryker Navigation stereotaxic adapter was functionally as accurate as the Stryker cutting guide system and could be used successfully in a navigated total knee arthroplasty without changes in accuracy. The second set of bench testing was used to show the accuracy of the subject device as it communicates with the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401) and the Stryker Navigation Unit (software versions 3.0 and 3.1). The accuracy was checked against the Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090).

Test #1

The navigation of cutting blocks at 15 degrees femoral hyperextension (end limit of device flexion) (SW 3.0) was conducted on both the Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090) and the subject device and the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401). Hyperflexion of 15 ° was chosen because it is the end limit of the iKnee Distal Femoral Cutting Guide and we wanted to show that at the end limits there is no loss of accuracy compared to the Stryker cutting block even though clinically a surgeon would not choose to put the implants in at 15 ° hyperflexion. The objective of this test was to show that the accuracy of the subject device as it communicates with the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401) and the Stryker Navigation Unit is as accurate as the Stryker

Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090).

Conclusion:

This test provided consistent information with no significant error between the two devices. This test showed that the iKnee Distal Femoral Cutting Guide is an accurate alternative to the Stryker cutting system and can be used during a navigated total knee arthroplasty with no loss in accuracy.

Test #2

Toggle Test (SW 3.0) was performed at 0° femoral flexion for the subject device and the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401), the Stryker MIS Navigated Distal Femoral Cutting Block (6541-5-721) and Stryker Navigation Navigated Tracker Adapter (6541-004-401) and the Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090). The objective of this test was to show that the rotation of the Stryker Tracker assembly along the cutting surface plane, while attached to the mounting hole of the iKnee cutting block, would not affect system accuracy, and would have equivalent accuracy to the Stryker system with a similar rotation of the tracker assembly.

Conclusion:

This test provided consistent information with no significant error between the two devices. This showed that the iKnee Distal Femoral Cutting Guide is an accurate alternative to the Stryker cutting system and can be used during a navigated total knee arthroplasty with no loss in accuracy.

Test #3

The navigation of cutting blocks at 0 ° femoral flexion (SW 3.1) was conducted on both the Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090) and the subject device and the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401). The objective of this test was to show that the accuracy of the subject device as it communicates with the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401) and the Stryker Navigation Unit is as accurate as the Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090). 0 ° flexion was chosen because it is more consistent with what a surgeon would choose for their implant position and we wanted to show that clinically the subject device is as accurate as the Stryker cutting block system.

Conclusion:

This test provided consistent information with no significant error between the two devices. This test showed that the iKnee Distal Femoral Cutting Guide is an accurate alternative to the Stryker cutting system and can be used during a navigated total knee arthroplasty with no loss in accuracy.

Test #4

The navigation of the height of the medial and lateral femoral condyles (SW 3.1) was conducted with the subject device and the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401) and the Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090). The objective of this test was to show that linear measurement of depth between the two cutting devices were consistent between the two with no increased error using the subject device and the Stryker Navigation Navigated Tracker Adapter (item number 6541-004-401) compared to the Stryker Navigation Distal Femoral Cutting Guide (item number 6003-100-050) and Stryker Navigation Tracker Adapter (6003-100-090).

Conclusion:

This test provided consistent information with no significant error between the two devices. This test showed that the iKnee Distal Femoral Cutting Guide is an accurate alternative to the Stryker cutting system and can be used during a navigated total knee arthroplasty with no loss in accuracy.